

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
***SAN DIEGO HOSPITAL ASSOCIATION,***  
***SHARP MEMORIAL HOSPITAL AND GROSSMONT HOSPITAL CORPORATION***

**I. PREAMBLE**

San Diego Hospital Association ("SDHA"), Sharp Memorial Hospital and Grossmont Hospital Corporation (collectively "Sharp") hereby enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). Contemporaneously with this CIA, Sharp is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to execution of this CIA, Sharp was subject to two separate CIAs with HHS-OIG for conduct occurring at Sharp Memorial Hospital and Grossmont Hospital Corporation respectively. These two hospitals are also subject to this CIA. Prior to the execution of this CIA, SDHA established a corporate compliance program ("Compliance Program") that applies to all Sharp's subsidiaries and facilities, including the entities subject to this CIA. The Compliance Program establishes corporate integrity policies and procedures and is aimed in part at ensuring that Sharp's participation in Federal health care programs is in conformity with the statutes, regulations, and other directives applicable to the programs. Sharp agrees that during the term of this CIA it will continue to operate its Compliance Program in a manner that meets the requirements of this CIA. Sharp may modify the Compliance Program as appropriate, but at a minimum, Sharp shall ensure that it complies with the integrity obligations that are enumerated in this CIA.

## **II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Sharp under this CIA shall be 5 years from the effective date of this CIA ("Effective Date") (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Sharp's final annual report; or (2) any additional materials submitted by Sharp pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:
  - a. all officers, directors, and employees of Sharp;
  - b. any agent, contractor or other individual who participates in the process of preparing claims, cost reports or other requests for reimbursement from any Federal health care program on behalf of Sharp; and
2. "Covered Contractor" includes:
  - a. an entity (or individual) that, although not a Covered Person, has entered into a written contract with Sharp to provide patient care to Federal health care program beneficiaries in Sharp facilities.
3. "Relevant Covered Persons" includes those individuals who participate in the process of preparing claims, cost reports or other requests for reimbursement from any Federal health care program on behalf of Sharp.

For the purposes of this CIA, the definition of "Covered Persons" excludes housekeeping staff, dietary employees, maintenance workers, construction workers, plant operations

workers, grounds keeping workers, security staff, gift shop employees, library employees and mail room employees.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Sharp shall maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee.**

1. *Compliance Officer.* Sharp has designated an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of SDHA, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of SDHA, and shall be authorized to report on such matters to the SDHA Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Sharp as well as for any reporting obligations created under this CIA.

Sharp shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Sharp's Compliance Committee shall remain in existence and its membership shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Sharp shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance

Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* Sharp has established a written Code of Conduct. To the extent not already accomplished within 150 days prior to the Effective date, the Code of Conduct shall be distributed to all Covered Persons within 150 days after the Effective Date. Sharp shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Sharp's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. Sharp's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Sharp's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Sharp's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Sharp suspected violations of any Federal health care program requirements or of Sharp's own Policies and Procedures;
- d. the possible consequences to both Sharp and Covered Persons of failure to comply with Federal health care program requirements and with Sharp's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Sharp's commitment to maintain

confidentiality, as appropriate, and nonretaliation with respect to such disclosures.

To the extent not already accomplished within 150 days prior to the Effective Date, within 150 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Sharp's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 150 days after the Effective Date, whichever is later.

Sharp shall, at a minimum, annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days after finalizing such changes. Each Covered Person shall certify that he or she has received, read, understood, and shall abide by the revised Code of Conduct within the course of Sharp's corporate compliance training.

2. *Policies and Procedures.* To the extent not already accomplished within 150 days prior to the Effective Date, within 150 days after the Effective Date, Sharp shall implement written policies and procedures ("Policies and Procedures") regarding the operation of Sharp's Compliance Program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the procedures for the proper and accurate preparation of cost reports, including the proper reporting of contingent liabilities, reserves, and adjustments to such reports submitted to any Federal health care program by or on behalf of Hospitals;
- c. the procedures for proper and timely refunding of any overpayments (as defined in Section III.F.1.a.) received from a Federal health care program by Hospitals;
- d. the commitment of Sharp to remain current with all Federal health care program requirements by obtaining and reviewing program

memoranda, bulletins, newsletters, or other correspondence from the Fiscal Intermediary related to Federal health care program requirements;

e. the Disclosure Program as described in Section III.F; and

f. the review and removal of Ineligible Persons as described in Section III.D.

Within 150 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable Sharp staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Sharp shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures.

### C. Training and Education.

1. *General Training.* To the extent not already accomplished within 150 days prior to the Effective Date, within 150 days after the Effective Date, Sharp shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain Sharp's:

a. the existence of the CIA and Sharp's obligations thereunder; and

b. Sharp's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within 30 days after becoming a Covered Person or within 150 days after the Effective Date, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

## *2. Specific Training*

*A. Cost Report Training Module.* Within 120 days after the Effective Date, each Relevant Covered Person involved in cost reporting activities shall receive at least 4 hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

- a. the submission of proper and accurate cost reports to Federal health care programs;
- b. the proper and accurate characterization of contingent liabilities, reserves and adjustments to Federal health care program cost reports;
- c. the proper and timely refunding of overpayments and settlements received from Federal health care programs;
- d. the personal obligation of each Relevant Covered Person involved in the cost reporting, billing, or refunding/reconciliation process to ensure that such cost reports, billings, or refunds are accurate;
- e. applicable reimbursement statutes, regulations, and program requirements and directives related to cost reports;
- f. the legal sanctions for submission of improper cost reports or billings, or the failure to appropriately and timely refund overpayments received from Federal health care programs; and
- g. examples of proper and improper cost reporting practices.

*B. Coding and Billing Training Module.* Within 120 days after the Effective Date, each Relevant Covered Person involved in coding and billing activities shall receive at least 4 hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

- a. the submission of accurate claims for services rendered to Federal health care program beneficiaries;

- b. policies, procedures, and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper claims; and
- f. examples of proper and improper claims submission practices.

Persons providing the training shall be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 150 days after the Effective Date, whichever is later. A Sharp employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, each Relevant Covered Person shall receive at least 2 hours of specific training annually. Sharp shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, and any other relevant information.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Covered Contractor Requirements.

Within 120 days after the Effective Date, Sharp shall use its best efforts to obtain written documentation from each Covered Contractor showing:

1. Code of Conduct. That the Covered Contractor has received and read Sharp's Code of Conduct and that the Covered Contractor understands that Sharp's Code of Conduct applies to the Covered Contractor.

2. Policies and Procedures. That the Covered Contractor has received and read Sharp's Policies and Procedures, applicable to the job functions for which the Covered Contractor has been engaged.

3. Confidential Disclosure Program. That the Covered Contractor has received notice of and education on the appropriate use of the Confidential Disclosure Program.

4. General Training. That Sharp has made General Training available to each Covered Contractor.

Sharp shall use its best efforts to obtain the written documentation requested in this Section III.C from each new Covered Contractor within 30 days after commencing work for Sharp or within 120 days after the Effective Date, whichever is later.

The Compliance Officer (or his or her designee) shall retain: (1) the written documentation from each Covered Contractor; and (2) a list of Covered Contractor who receives General Training. These shall be made available to OIG, upon request.

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days after the Effective Date, Sharp shall select an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Sharp in assessing and evaluating its billing, coding and cost

reporting practices and certain other obligations pursuant to this CIA and the Settlement Agreement. The OIG must approve Sharp's selection of the IRO prior to its engagement. Each IRO retained by Sharp shall have expertise in the billing, coding, reporting, or other requirements of hospital operations and in the general requirements of the Federal health care program(s) related to the IRO's engagement from which Sharp seeks reimbursement. Each IRO shall assess, along with Sharp, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist. In accordance with Appendix A, the IRO(s) review shall address and analyze cost reporting practices that involve the Federal health care programs ("Cost Report Review and Cost Report Systems Review"), Sharp's billing and coding to the Federal health care programs ("Claims Review") and shall review whether Sharp sought payment for certain unallowable costs ("Unallowable Cost Review") as set forth in the Settlement Agreement.

b. Frequency of Cost Report Review. The Cost Report Review shall be performed for the first, second and fourth Reporting Periods. The OIG, at its sole discretion, shall require additional Cost Report Reviews for the third and fifth Reporting periods. The IRO(s) shall perform all components of each Cost Report Review.

c. Frequency of Claims Review. The Claims Review shall be performed for the third and fifth Reporting Periods and shall cover the one-year periods of the CIA beginning with the Effective Date of this CIA. The IRO(s) shall perform all components of each Claims Review.

d. Frequency of Unallowable Cost Review. The IRO shall perform the Unallowable Cost Review for the first Reporting Period.

e. Retention of Records. The IRO and Sharp shall retain and make available to OIG, upon request, all work papers, supporting

documentation, correspondence, and draft reports (those exchanged between the IRO and Sharp) related to the reviews.

2. *Cost Report Process Review.* Within 60 days after the retention of the IRO, the IRO shall review Sharp's cost report preparation process (the "Process Review"). The Process Review shall consist of a thorough review of (i) Sharp's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs, and (ii) SDHA's home office cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps Sharp takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

3. *Process Review Report.* Within 180 days after the Effective Date, the IRO shall prepare a report based upon the Process Review performed ("Process Review Report"). The Process Review Report shall include the IRO's findings and supporting rationale regarding:

- a. the strengths and weaknesses in (i) Sharp's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs, and (ii) Sharp's home office cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs; and
- b. any recommendations the IRO may have to improve any of these systems, operations, and processes.

4. *Cost Report Review.* In addition to the Cost Report Process Review described above, the IRO shall also perform a review that, at a minimum includes the procedures outlined in Appendix A ("Cost Report Review").

5. *Cost Report Review Report.* The IRO shall prepare a report based upon the Cost Report Review. The Cost Report Review Report shall include the IRO's findings and supporting rationale regarding:

- a. the strengths and weaknesses in Sharp's cost report, cost statement, information statement, and payment request preparation processes relating to any and all costs submitted to Federal health care programs;
- b. any recommendations the IRO may have to improve any of these systems, operations, and processes; and
- c. a summary of the conclusions from the Cost Report Review.

6. *Claims Review.* The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this CIA, which is incorporated by reference.

- a. Discovery Sample. The IRO shall select and review two samples of 50 Medicare Paid Claims submitted by or on behalf of Sharp. The IRO and Sharp shall consult with the OIG prior to the selection of the Discovery Samples to determine the Sharp entity and the type of Medicare Paid Claims to be selected. The Paid Claims shall be reviewed based on the supporting documentation available at Sharp or under Sharp's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.
  - i. If the Error Rate (as defined in Appendix B) for each Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Sharp should, as appropriate, further analyze any errors identified in the Discovery Sample. Sharp recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority, may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)
  - ii. If one of the Discovery Samples indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample for

that Discovery Sample in which the Error Rate is 5% or greater and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix B. The Full Sample shall be designed to (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Sharp or under Sharp's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Sharp may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. OIG, in its full discretion, may refer the findings of the Full Sample (and any related work papers) received from Sharp to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If one of Sharp's Discovery Samples identifies an Error Rate of 5% or greater, Sharp's IRO shall also conduct a Systems Review. Specifically, for each claim in that Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with Section III.H.1, Sharp shall repay any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Sharp shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

7. *Claims Review Report*. The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix B.

8. *Unallowable Cost Review*. The IRO shall conduct a review of Sharp's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Sharp has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Sharp or any of its subsidiaries. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

9. *Unallowable Cost Review Report*. The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether Sharp has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

10. *Validation Review.* In the event OIG has reason to believe that: (a) Sharp's Cost Report Review, Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Cost Report and Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Cost Report Review, Claims Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings of the Cost Report or Claims Review results are inaccurate ("Validation Review"). Sharp shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Sharp's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Sharp of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Sharp may request a meeting with OIG to discuss the results of any Cost Report Review, Claims Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Cost Report Review, Claims Review or Unallowable Cost Review or to correct the inaccuracy of the Cost Report Review or Claims Review; or propose alternatives to the proposed Validation Review. Sharp shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Cost Report Review, Claims Review or Unallowable Cost Review with Sharp prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

11. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to Sharp a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Cost Report Review, Claims Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

#### F. Disclosure Program.

Within 90 days after the Effective Date, Sharp shall maintain a Disclosure Program, which shall include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions

associated with Sharp's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law. Sharp shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Sharp shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

#### G. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

2. *Screening Requirements.* Sharp shall ensure that all owners, officers, directors, employees, contractors, agents of Sharp are not Ineligible Persons. To ensure that such persons are not Ineligible Persons ("Persons"), Sharp shall screen such Persons prior to engaging their services by: (a) requiring such persons to disclose whether they

are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) Sharp to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 90 days after the Effective Date, Sharp shall review its list of the Persons identified in Section G.2 against the Exclusion Lists. Thereafter, Sharp shall review its list of such persons against the Exclusion Lists annually. In addition, Sharp shall require such Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If Sharp has actual notice that such person has become an Ineligible Person, Sharp shall remove such person from responsibility for, or involvement with, Sharp's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Sharp has actual notice that a person identified in Section G.2 is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, contract term, Sharp shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

5. *Physicians with Staff Membership.* Prior to granting staff membership to a physician after the Effective Date, Sharp shall screen in the manner described in Section III.F.2 above to determine if the physician is an Ineligible Person. Furthermore, Sharp shall review its list of physicians with staff membership against the Exclusion Lists within 90 days after the Effective Date, and, at least annually thereafter, Sharp shall screen said physician member against the Exclusion lists. If Sharp determines that a

physician with staff membership is an Ineligible Person, Sharp shall take appropriate measures in accordance with applicable law. Sharp shall ensure that any physician who is an Ineligible Person does not contract with Sharp or any of its providers of “on call” services at Sharp.

#### H. Notification of Government Investigation or Legal Proceedings.

Within 60 days after discovery, Sharp shall notify OIG, in writing, of any ongoing investigation known to Sharp or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Sharp has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Sharp shall also provide written notice to OIG within 60 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

#### H. Reporting.

##### 1. *Overpayments*

a. Definition of Overpayments. For purposes of this CIA, an “Overpayment” shall mean the amount of money Sharp has received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, Sharp identifies or learns of any Overpayment, Sharp shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Sharp shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Sharp shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when

such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

## *2. Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means anything that involves:

- i. a substantial Overpayment;
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or

A Material Deficiency may be the result of an isolated event or a series of occurrences.

b. Reporting of Material Deficiencies. If Sharp determines through any means that there is a Material Deficiency, Sharp shall notify OIG, in writing, within 30 days after making the determination that the Material Deficiency exists. The report to OIG shall include the following information:

- i. If the Material Deficiency results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Sharp's actions taken to correct the Material Deficiency; and

iv. any further steps Sharp plans to take to address the Material Deficiency and prevent it from recurring.

#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date, Sharp changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Sharp shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at each such business unit or location shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 150 days after the Effective Date, Sharp shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. a copy of Sharp's Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2;
5. a copy of all training materials used for the training required by Section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:
  - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
  - b. all Covered Persons have completed the Code of Conduct certification required by Section III.B.1; and
  - c. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Disclosure Program required by Section III.E;
8. the identity of the IRO(s), a summary/description of all engagements between Sharp and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and

completion dates of the Cost Report Review, Claims Review, Unallowable Cost Review, or Systems Review;

9. a certification from the IRO regarding its professional independence and/or objectivity with respect to Sharp;

10. a summary of personnel actions (other than hiring) taken pursuant to Section III.F.;

11. a list of all of Sharp's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s), and the name and address of the Medicare contractor to which Sharp currently submits claims;

12. a description of Sharp's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

13. the certification required by Section V.C.

B. Annual Reports. Sharp shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Sharp's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct certifications required by Section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C;

c. Sharp has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

4. a copy of all training materials used for the training required by Section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's cost report review, claims review, unallowable cost review and cost report systems review, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. Sharp's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a revised summary/description of all engagements between Sharp and the IRO, including, but not limited to, any outside financial audits,

compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and/or objectivity with respect to Sharp;

9. a summary of Material Deficiencies (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

11. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

12. a description of any personnel actions (other than hiring) taken by Sharp as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F., and the actions taken in response to the obligations set forth in that Section;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a description of all changes to the most recently provided list (as updated) of Sharp's locations (including addresses) as required by Section V.A.11, the corresponding name under which each location is doing

business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s), and the contractor name and address that issued each Medicare provider number; and

15. the certification required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, Sharp is in compliance with all of the requirements of this CIA; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information. Sharp shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Sharp shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Telephone: 202.619.2078  
Facsimile: 202.205.0604

Sharp:

Paul Belton  
Vice President, Corporate Compliance  
Sharp HealthCare  
8695 Spectrum Center Court  
San Diego, California 92123  
Phone: 858-499-4015

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

**VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Sharp's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Sharp's locations for the purpose of verifying and evaluating: (a) Sharp's compliance with the terms of this CIA; and (b) Sharp's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Sharp to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Sharp's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Sharp shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Sharp acknowledges that employees may elect to be interviewed with or without a representative of Sharp present.

## **VIII. DOCUMENT AND RECORD RETENTION**

Sharp shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 years (or longer if otherwise required by law).

## **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Sharp prior to any release by OIG of information submitted by Sharp pursuant to its obligations under this CIA and identified upon submission by Sharp as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Sharp shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

Sharp is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Sharp and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Sharp fails to have in place any of the obligations described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Sharp fails to retain an IRO, as required in Section III.D.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Sharp fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Sharp employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, Sharp's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Sharp can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).

5. A Stipulated Penalty of \$1,500 for each day Sharp fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Sharp fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Sharp as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Sharp fails to comply fully and adequately with any obligation of this CIA. In its notice to Sharp, OIG shall state the specific grounds for its determination that Sharp has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Sharp shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Sharp receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall

not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Sharp may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Sharp fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Sharp receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Sharp has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Sharp of: (a) Sharp's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Sharp shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Sharp elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Sharp cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Sharp has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Sharp to report a Material Deficiency, take corrective action, and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to retain and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Sharp constitutes an independent basis for Sharp's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Sharp has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Sharp of: (a) Sharp's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Sharp shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Sharp is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Sharp has begun to take action to cure the material breach; (ii) Sharp is pursuing such action with due diligence; and (iii) Sharp has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Sharp fails to satisfy the requirements of Section X.D.3, OIG may exclude Sharp from participation in the Federal health care programs. OIG shall notify Sharp in writing of its determination to exclude Sharp (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Sharp may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Sharp of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Sharp shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42

C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Sharp was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Sharp shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Sharp to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Sharp requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Sharp was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Sharp had begun to take action to cure the material breach within that period; (ii) Sharp has pursued and is pursuing such action with due diligence; and (iii) Sharp provided to OIG within that period a reasonable timetable for curing the material breach and Sharp has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Sharp, only after a DAB decision in

favor of OIG. Sharp's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Sharp upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Sharp may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Sharp shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Sharp, Sharp shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

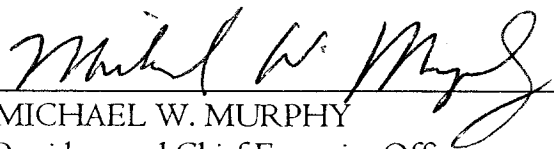
#### **XI. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Sharp and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Sharp;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. OIG may agree to a suspension of Sharp's obligations under the CIA in the event of Sharp's cessation of participation in Federal health care programs. If Sharp withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Sharp shall notify OIG at least 30 days in advance of Sharp's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Sharp signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF SHARP



MICHAEL W. MURPHY  
President and Chief Executive Officer  
San Diego Hospital Association

2/17/03  
DATE



DANIEL L. GROSS  
Chief Executive Officer  
Sharp Memorial Hospital

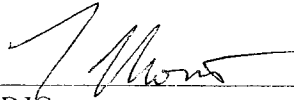
2/17/03  
DATE



MICHELE TARBET  
Chief Executive Officer  
Grossmont Hospital Corporation

2/17/03  
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



LEWIS MORRIS

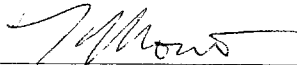
Chief Counsel to the Inspector General

Office of Inspector General

U. S. Department of Health and Human Services

2/21/09  
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



LEWIS MORRIS

Chief Counsel to the Inspector General

Office of Inspector General

U. S. Department of Health and Human Services

2/21/03  
DATE

## **APPENDIX A**

### **Cost Reporting Review Procedures**

The following procedures represent the minimum expectations for performance by the IRO in meeting the objectives of Section III.E.4.

A. For any year in which a Cost Report review is required, the IRO shall conduct a Medicare hospital cost report review for Sharp Memorial Hospital, Grossmont Hospital and a home office cost report review for San Diego Hospital Association (collectively the three cost reporting entities will be referred to as “Sharp”).

B. These Medicare Cost Report Reviews shall include tests of square footage statistics, payroll costs, other operating costs, the proper classification of costs as reported in the general ledger and the proper placement of revenue and costs associated with ancillary services in the proper cost centers. Procedures to be performed include:

1. Review the cost reports selected under I.A. of Appendix A and related working papers prepared and filed for the audit year for completeness and accuracy;
2. Select a minimum of three cost centers and trace the accounts included in the cost center to Sharp’s general ledger;
3. Interview the Sharp representatives responsible for submission and compilation of data used in preparation of the annual Medicare cost reports, including the preparation of supporting work papers, in order to evaluate the integrity of the data collection and reporting process underlying those reports;
4. Review organ transplant costs at Sharp Memorial Hospital to ensure that they are allowable as such and were properly allocated between the various organ types and between pre-transplant and post-transplant. This review should determine, at a minimum, whether:
  - a. Physician fees (a.k.a., medical director fees) are supported by invoices for the allocation between pre-transplant and post-transplant amounts.
  - b. Salary costs were allocated between the various organ types and between pre-transplant and post-transplant based on actual time or qualified time studies.
  - c. Costs allocated to organ acquisition from other departments (HLA lab, HHA, etc.) was appropriate.
  - d. Overhead allocated to the transplant department was properly allocated between pre-transplant and post-transplant using a CMS approved method.

5. Review Worksheet A-6, A-8, and any other necessary Worksheets to ensure that Sharp is properly incorporating the Medicare fiscal intermediary adjustments in the preparation of its cost reports; and
6. Review the Cost Report Form HCFA 339 for accuracy and completeness.
7. In the first and fourth reporting periods, the IRO shall perform a comparison analysis of the current year's cost report to the prior year's cost report for each of the following items:
  - a. Compare Worksheet A expenses by cost centers. For increases or decreases of 25% or greater, follow up with Sharp to obtain an explanation.
  - b. To ensure consistency of cost classifications, compare account groupings by cost center. If costs have been grouped inconsistently follow up with Sharp as to the reason for the inconsistency and verify that the fiscal intermediary has approved such changes in grouping.
  - c. Compare the accounts included in the Administrative and General ("A&G") cost center. Perform detailed testing on accounts included in the A&G cost center that may be highly susceptible to abuse or misallocation of costs (e.g., recruiting, marketing, physician-related costs, relocation costs, etc.).
  - d. Compare Worksheet A-6 cost reclassifications.
  - e. Compare Worksheet A-8 cost adjustments.
  - f. Compare the cost to charge ratios by cost center on Worksheet C. For increases or decreases of 25% or greater, follow up with Sharp to obtain explanations.

## APPENDIX B

### A. Claims Review.

1. **Definitions.** For the purposes of the Claims Review the following definitions shall be used:

- a. Overpayment: The amount of money Sharp has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Paid Claim: A code or line item submitted by Sharp for treatment and for which Sharp has received reimbursement from the Medicare program.
- d. Population: All Items for which Sharp has submitted a code or line item and for which Sharp has received reimbursement from the Medicare program for treatment (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

### 2. **Other Requirements.**

- a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Sharp cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Sharp for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

**B. Claims Review Report.** The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

**1. Claims Review Methodology.**

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term “Item” may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

b. Claims Review Population. A description of the Population subject to the Claims Review.

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

## **2. Claims Review Findings.**

- a. a description of Sharp's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;
- b. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation; and
- c. the IRO's findings and recommendations concerning the Systems Review (if any).

## **3. Statistical Sampling Documentation.**

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

#### **4. Claims Review Results.**

- a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Sharp (“Claims Submitted”) differed from what should have been the correct claim (“Correct Claim”), regardless of the effect on the payment.
- b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Sharp.
- c. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- d. Error Rate in the sample.
- e. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

**5. Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.

**6. Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

## OVERPAYMENT REFUND

**TO BE COMPLETED BY MEDICARE CONTRACTOR**

Date: \_\_\_\_\_  
 Contractor Deposit Control # \_\_\_\_\_ Date of Deposit: \_\_\_\_\_  
 Contractor Contact Name: \_\_\_\_\_  
 Phone # \_\_\_\_\_  
 Contractor Address: \_\_\_\_\_  
 Contractor Fax: \_\_\_\_\_

**TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER**

*Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.*

PROVIDER/PHYSICIAN/SUPPLIER NAME \_\_\_\_\_  
 ADDRESS \_\_\_\_\_  
 PROVIDER/PHYSICIAN/SUPPLIER # \_\_\_\_\_  
 CHECK NUMBER# \_\_\_\_\_  
 CONTACT PERSON: \_\_\_\_\_  
 PHONE # \_\_\_\_\_ AMOUNT OF CHECK \$ \_\_\_\_\_  
 CHECK DATE \_\_\_\_\_

**REFUND INFORMATION**

**For each Claim, provide the following:**

Patient Name \_\_\_\_\_  
 HIC# \_\_\_\_\_  
 Medicare Claim Number \_\_\_\_\_  
 Claim Amount Refunded \$ \_\_\_\_\_  
 Reason Code for Claim Adjustment: \_\_\_\_\_ (Select reason code from list below. Use one reason per claim)

*(Please list all claim numbers involved. Attach separate sheet, if necessary)*

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: \_\_\_\_\_*

**For Institutional Facilities Only:**

Cost Report Year(s) \_\_\_\_\_  
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

**For OIG Reporting Requirements:**

Do you have a Corporate Integrity Agreement with OIG? Yes No

**Reason Codes:**

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify) _____
06 - Billed in Error		
07 - Corrected CPT Code		

[illegible]